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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,775	10/31/2003	John J. Allen	LFS-5016	2856

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EXAMINER	
NGUYEN, HUONG Q	
ART UNIT	**PAPER NUMBER**
3736	

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12/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/698,775	ALLEN, JOHN J.	
	Examiner	Art Unit	
	Helen Nguyen	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 10-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 10-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/28/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the amendment filed 10/8/2007. Claims 1 and 11 are amended. **Claims 1-6 and 10-13** remain pending.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 9/28/2007 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. **Claims 1-2, 5, 10-12** are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakata et al (US Pub No. 20040215224) in view of Perez et al ((US Pub No. 20020188223).

5. In regards to **Claim 1**, Sakata et al disclose a lancing device comprising:

a housing (2) formed with a "cylindrical member" (20) (¶0063);

a lancing mechanism (3) operatively attached to the housing (¶0067);

a pressure tip, referred to as a "cylindrical member" (8) including an "analysis sensor" (4), moveably attached to the housing for engaging a target site and creating a target site bulge upon being urged toward the target site, wherein Sakata et al disclose pressing said pressure tip against the skin target site, which would contribute to the creation of a target site bulge (¶0080, 0081);

a trigger mechanism comprising of a "sensor holder" (7B) and "pivot member" (79) for detecting a target site bulge of a predetermined height created by the urging of the pressure tip against the target site, wherein the urging of the pressure tip against the target site contributes to the creation of said target site bulge, and triggering a releasable immobilization of the pressure tip with respect to the housing. Because the pressure tip is defined with the "analysis sensor" (4) and said sensor becomes immobilized at a predetermined angle, which depends upon the degree of skin bulging, the pressure tip is considered to immobilize as a whole (¶0110, 0111). Please see Figure 19 for a detailed drawing. The immobilization is releasable in that a change in pressure within the pressure tip releases said immobilization (¶0112).

6. However, Sakata et al do not disclose triggering a locked releasable immobilization of the pressure tip that includes locked releasable immobilization of longitudinal movement of the pressure tip within the housing. Perez et al teach the locked immobilization of a pressure tip (49) that includes locked immobilization of longitudinal movement of the pressure tip within the housing (48), best seen in Figures 19-20, to effectively form a target site bulge and facilitate bodily fluid retention in the bulge for subsequent lancing and ease of removal (¶0083-0088). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the trigger mechanism of Sakata et al to include a locked immobilization of

longitudinal movement of the pressure tip within the housing occurs, as taught by Perez et al, such that in combination Sakata et al and Perez et al teach a releasably locked immobilization of the pressure tip with respect to the housing that includes releasably locked immobilization of longitudinal movement of the pressure tip within the housing, to further enhance the formation of the target site bulge and prevent subsequent change in the target site bulge location for effective lancing and subsequent body fluid removal.

7. In regards to **Claim 2**, Sakata et al disclose a bias spring (83) for applying a pre-load force against the cylindrical member (8) of the pressure tip (Figure 19), as defined above.

8. In regards to **Claim 5**, Sakata et al disclose a trigger mechanism including at least one locking pawl (7B) and at least one pawl trigger arm (79) wherein the "pivot member" (79) and "sensor holder" (7B), which includes "stopper" (77a), perform a motion-deterring function and thus are considered as pawls (¶0110).

9. In regards to **Claim 10**, Sakata et al disclose the trigger mechanism configured to initiate lancing by the lancing mechanism once the pressure tip has been immobilized, as described previously (¶0082, 0084).

10. In regards to **Claim 11**, Sakata et al in combination with Perez et al disclose a method for lancing a target site comprising:

providing a lancing device that includes a housing (2, 20), a lancing mechanism (3) operatively attached to the housing, a pressure tip (4, 8 as defined above) moveably attached to the housing for engaging a target site and creating a target site bulge upon being urged toward

the target site as explained in the rejection of **Claim 1** above, and a trigger mechanism (7B, 79) for detecting a target site bulge of a predetermined height created by the urging of the pressure tip against the target site as previously detailed and thereafter, triggering a releasably locked immobilization of the pressure tip with respect to the housing that includes releasably locked immobilization of longitudinal movement of the pressure tip within the housing as elaborated in the above rejection of **Claim 1**, thereby preventing a subsequent change in target site bulge location relative to said housing;

contacting the pressure tip with the target site (¶0080);

urging the pressure tip towards the target site, thereby creating target site bulge (¶0081) that is detected by the trigger mechanism (7B, 79) and triggering the locked immobilization of the pressure tip with respect to the housing, as described above (¶0110, 0111);

lancing the target site bulge with the lancet mechanism (¶0082, 0084).

11. In regards to **Claim 12**, Sakata et al disclose the target site as a dermal tissue target site, skin S (¶0080).

12. In regards to **Claim 13**, Sakata et al disclose providing a lancing device that includes a bias spring (83) for applying a pre-load force against the cylindrical member (8) of the pressure tip, as explained previously (Figure 19).

13. **Claims 3,4** are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakata et al in view of Perez et al, further in view of Schmelzeisen-Redeker et al (US Pat No. 6589260).

14. Sakata et al disclose a spring (83) to apply a pre-load force against the pressure tip but do not specify the specific strength of the spring. Schmelzeisen-Redeker et al disclose a lancing device with a spring that supplies a force of 10-15 N to optimally control the pressing force needed to operate the lancet (Col.7 line 58-65, Col.8 line 26-30). Therefore, it would have obvious to one of ordinary skill in the art at the time the invention was made to modify the spring disclosed by Sakata et al as modified by Perez et al to provide a force within the ranges of 3-13 N and 9-10 N, as taught by Schmelzeisen-Redeker et al, to provide a sufficient amount of force to operate the lancing device, including that necessary to create a desired target site bulge.

15. **Claim 6** is rejected under 35 U.S.C. 103(a) as being unpatentable over Sakata et al in view of Perez et al, further in view of Shraga (US Pub No. 2005/0038465).

16. Sakata et al disclose a locking pawl (7B) with stopper (77a) but do not disclose the pawl having multiple ratchet teeth. Sakata et al also do not disclose the pressure tip having ratchet teeth, wherein the pressure tip is defined to include "analysis sensor" (4), which is attached to "pivot member" (79), therefore constituting pivot member as a part of the pressure tip (Figure 19). Shraga discloses a lancet device that uses ratchet teeth to engage pawls as an effective method to maintain the depth setting, shown in Figures 47-50 (¶0124 and 0125). Therefore, it would have obvious to one of ordinary skill in the art at the time the invention was made to modify the locking pawl (7B) and the pivot member (79) of the pressure tip, as disclosed by Sakata et al as modified by Perez et al, to both include multiple ratchet teeth as further taught by Shraga, to enhance the immobilization mechanism disclosed by providing a more fitted

engagement of the stopper (77a) of the locking pawl (7B) against the pivot member (79) of the pressure tip during immobilization to create a superior trigger mechanism.

Response to Arguments

17. Applicant's arguments filed 10/8/2007 have been fully considered but they are not persuasive. Applicant contends that neither Sakata et al nor Perez et al teach the releasably locked immobilization of the pressure tip. However, as elaborated above, it is noted that Sakata et al already teach a releasable immobilization of the pressure tip as defined above (¶0112), as also admitted by Applicant in the remarks dated 1/8/2007 p.2 first paragraph. Since Perez et al teach the recited locked immobilization, it is obvious to one of ordinary skill in the art that in combination, Sakata et al and Perez et al will together teach the claimed releasably locked immobilization of the pressure tip as motivated by the reasons described above.

18. It is also noted that the recite term "releasably locked immobilization" negates the weight of the term "locked," thus implying to one of ordinary skill in the art a mechanism that is simply releasably immobilized, which is already taught by Sakata et al.

Conclusion

19. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is 571-272-8340. The examiner can normally be reached on Monday - Friday, 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

HQN
12/21/2007